SWEDISH MEDICAL CENTER
CHERRY HILL CAMPUS

September 28, 2007

Mr. Bart Egan
Director, Facilities and Services Licensing
Washington Department of Health
MS: 7852
PO Box 47852
Olympia WA 98504-7852

Dear Mr. Egan:

We want to thank you for providing Swedish Health Services the opportunity to offer additional recommendations regarding the drafting of Certificate-of Need ("CN") rules that would allow elective percutaneous coronary interventions ("PCI") without on-site cardiac surgery back-up. We endorse the recently-completed "Adult Elective Percutaneous Coronary Interventions in Hospitals Without Cardiac Surgery" report, prepared by Heath Management Associates ("HMA"), September, 2007. Their expert analysis, in our opinion, was completely consistent with legislative intent and the department's scope of work, specifically to:

> Conduct an evidence-based review and provide a report to the Department of Health, which 1) identifies the circumstances and makes recommendations which elective percutaneous coronary interventions should be allowed in Washington at hospitals that do not otherwise provide on-site cardiac surgery, and 2) what criteria must be met to determine which hospitals should be allowed to perform such procedures.

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We believe this analysis is the most complete we have had to-date, and forms a solid basis for health care decisions made on medical evidence, not anecdotes. This focuses the issues on the most critical matter---patient safety through best practices. This is essential as we move forward to consider CN rules and methodologies that would allow elective PCIs without on-site cardiac surgery back-up. Our collective goal must be providing the safest environments for PCI procedures for our citizens.

During the course of the debate regarding the critical issue of the rules governing elective PCI procedures, all sides of the issue agreed on one important matter; the *importance of requiring evidenced based scientific findings to guide our discussion and our ultimate decisions*. This focus has helped all of us define the most critical matter before us—patient safety through best practices. Our collective goal should be to protect citizens by providing the safest environments for PCI procedures while addressing other important matters such as medical costs and hospital volumes and revenue through a process that will provide both critical definition and protective procedures and requirements.

With these goals in mind we agreed to work with the Department of Health and other stakeholders to develop a new set of rules to reflect our evidence based findings and guide us to the best procedures, processes, licensing and other governance matters

pertaining to a patient-safety oriented set of heart rules for Washington. This goal has largely been achieved by the report before the Department of Health.

Additional Recommendations

As stated above, we concur with HMA recommendations. As with all science, however, this work is not complete; we have a number of additional recommendations. In the interest of helping to guide the rule-drafting process at this juncture, we state these recommendations as principles. As draft language is developed, we will be very willing to assist in refinement, based on these principles. They include:

1. Evidence-based decisions. High quality medicine is driven from evidence-based decisions, not anecdotal information.

2. Precise, measurable definition. Health Management Associates recommended a number of procedures for the "elective" PCI definition. This definition is pivotal and requires further refinement and precision. At a minimum, such a definition should not include diagnostic cardiac procedures nor should it include electrophysiology procedures. It must also be robust across inpatient and outpatient cases.

3. State agency authority and oversight based on clear rules and quantitative information.

4. Minimum data set requirements for all PCI procedures.

5. Provision of charity care specific to provision of PCI procedures.

6. Public access to PCI utilization statistics.

7. Performance metrics. HMA has defined utilization and volume metrics—an excellent start. This should include hospital and physician performance statistics.

8. Provider infrastructure and organization, including peer review and quality improvement committees.

9. Planning area definitions.

10. Centers of excellence.

Although not a part of the PCI rule-making process, as a policy and health planning issue, we would recommend additional financial analysis to

supplement that started by HMA in their report. Specifically, there needs to be empirical analysis to answer the following policy questions:

a. What are reasonable fixed and variable expenses associated with development/operation of primary and elective PCI programs. What does it cost to implement a PCI service—in capital, staffing, ancillary services needed, etc?
b. Is there a difference in fixed and variable costs for primary and elective PCI on a per case basis?
c. Are there economies of scale regarding delivery of PCIs? Are they material?
d. Is there a volume below which revenues will not cover variable and fixed costs, i.e., a program could generate contribution margin but incur operating losses?
e. What is the cost of adding elective PCI services to an organization that currently performs primary PCIs?
f. What current and expected staffing shortages exist and how will they affect financial performance?
g. Does payer mix matter across the state? If yes, why? How does/will it affect access?
h. What are reimbursement trends for major payers of PCIs?

We think from a health policy perspective, appropriate utilization of scarce resources to provide elective PCIs requires additional financial analysis regarding fiscal impacts and trade-offs. This work will be key in proper development of CN rules to guide implementation of elective PCIs.

We would be happy to answer any questions you have on the above recommendations. Thank you again for this opportunity to: (1) state for the record that the HMA study, in our opinion, met legislative intent—it is the most solid, evidence-based analysis of elective PCIs in our state to-date; and (2) offer additional recommendations, using the HMA analysis as a foundation.

Sincerely,

Howard Lewis, M.D.
Executive Director
Swedish Heart and Vascular Institute

Marcel Loh
Senior Vice President
Swedish Health Services